UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SHIRE LLC,	:	
	:	
Plaintiff,	:	**07 Civ. 3526 (MGC)**
	:	
v.	:	
	:	
TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTIICALS USA, INC.,	:	
	:	
Defendant.	:	
	:	

TEVA PHARMACEUTICALS USA, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S AMENDED COMPLAINT

Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA"), through its undersigned counsel, as and for its Answer, Defenses, and Counterclaims to the Complaint by Shire LLC ("Plaintiff"), responds as follows:

The Parties

1. Shire is a corporation organized and existing under the laws of the State of Kentucky, having its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042.

ANSWER: Teva USA. lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 1 of the Complaint and therefore denies the same.

2. Defendant Teva Ltd. is a corporation organized and existing under the laws of Israel, having its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

ANSWER: Admitted.

3. Defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

ANSWER: Admitted.

4. Teva USA is a wholly-owned subsidiary of Teva Ltd.

ANSWER: Teva USA admits that Teva Ltd. owns 100% of the ownership and voting interest in Teva USA and, except as so admitted, deny the allegations of paragraph 4 of the Complaint.

5. Unless otherwise stated, Teva Ltd. And Teva USA will be referred to collectively as "Teva."

ANSWER: Teva USA admits that Plaintiff collectively refers to Teva Ltd. and Teva USA as "Teva".

Nature of the Action

6. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 5,326,570 ("the '570 patent"); Exhibit A hereto.

ANSWER: Teva admits that this is an action for patent infringement under the patent laws of the United States, Title 35, United States Code in which Shire asserts claims of the '570 patent.

Jurisdiction and Venue

7. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 7 of the Complaint states a legal conclusion to which no response is required.

8. Upon information and belief, Teva Ltd. conducts business throughout the United States and specifically within New York.

ANSWER: Teva USA denies the allegations of paragraph 8 of the Complaint.

9. This Court has personal jurisdiction over Teva Ltd. because Teva Ltd. maintains sufficient minimum contacts, both generally and specifically, with this judicial district. The exercise of such jurisdiction is consistent with the requirements of due process and does not offend traditional notions of fair play and substantial justice.

ANSWER: Paragraph 9 of the Complaint states a legal conclusion to which no response is required.

10. Upon information and belief, Teva USA regularly conducts business throughout the United States and specifically derives substantial revenue from goods, food, services, or manufactured products used or consumed in New York, including but not limited to sales and distribution of drugs.

ANSWER: Teva USA admits that Teva USA regularly conducts business throughout the United States, including New York, and derives revenue from the sale and distribution of pharmaceutical products. Teva USA denies the remaining allegations of paragraph 4 of the Complaint.

11. This court has personal jurisdiction over Teva USA because Teva USA maintains sufficient minimum contacts, both generally and specifically, with this judicial district. The exercise of such jurisdiction is consistent with the requirements of due process and does not offend traditional notions of fair play and substantial

justice.

ANSWER: Paragraph 11 of the Complaint states a legal conclusion to which no response is required.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

ANSWER: Paragraph 12 of the Complaint states a legal conclusion to which no response is required.

Background

13. Shire is the owner of New Drug Application ("NDA") No. 20-712, which was approved by the Food and Drug Administration ("FDA") for the manufacture and sale of an extended-release capsule containing carbamazepine for the treatment of epilepsy and trigeminal neuralgia. Shire US, Inc. (a related company) markets and sells these compositions in the United States under the trade name Carbatrol®.

ANSWER: Teva USA admits that NDA No. 20-712 was approved by the FDA for the manufacture and sale of an extended-release capsule containing carbamazepine for the treatment of epilepsy and trigeminal neuralgia. Teva USA admits, on information and belief, that Shire US, Inc. markets and sells a carbamazepine product under the trade name Carbatrol®. Teva USA denies the remaining allegations of paragraph 13 of the complaint.

14. Upon information and belief, Teva USA submitted Abbreviated New Drug Application ("ANDA") No. 78-592 ("Teva's ANDA") to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of carbamazepine

extended-release capsules at the 100 mg, 200 mg, and 300 mg dosage strengths ("Teva's ANDA Products").

ANSWER: Admitted.

15. Teva USA sent Shire a "Patent Certification Notice -- U.S. Patent Nos. 5,326,570 and 5,912,013" pursuant to § 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)), dated March 20, 2007 ("Teva's Notice Letter" or "Notice Letter").

ANSWER: Admitted.

16. Upon information and belief, Teva Ltd. directed Teva USA to file ANDA No. 78-592, and Teva USA complied. Teva Ltd. also directed Teva USA to submit paragraph IV certifications concerning the '570 patent, and Teva USA also complied.

ANSWER: Teva USA admits that Teva USA filed ANDA No. 78-592. Teva USA also admits that Teva USA submitted paragraph IV certification concerning the '570 patent. Teva USA denies the remaining allegation of paragraph 16 of the Complaint.

17. Upon information and belief, Teva Ltd. and Teva USA were both aware of the '570 patent when Teva Ltd. directed Teva USA to file ANDA No. 78-592 and submit paragraph I'V certifications concerning the '570 patent.

ANSWER: Teva USA admits that Teva Ltd. and Teva USA were aware of the '570 patent when Teva USA filed ANDA No. 78-592 and submitted paragraph I'V certifications concerning the '570 patent. Teva USA denies the remaining allegations of paragraph 17 of the Complaint.

18. Upon information and belief, Teva Ltd. directed Teva USA to send Shire the Notice Letter and Teva USA complied.

ANSWER: Teva USA admits that Teva USA sent Shire the Notice Letter but denies the remaining allegations of paragraph 18 of the Complaint.

FIRST COUNT
(Infringement of the '570 Patent)

19. Shire repeats and realleges paragraphs 1 through 18 above as if fully set forth herein.

ANSWER: Teva USA reasserts and incorporates by reference each of the answers to paragraphs 1 through 18 above, as if fully set forth herein.

20. The '570 patent, entitled "Advanced Drug Delivery System And Method Of Treating Psychiatric, Neurological And Other Disorders With Carbamazepine," was duly and legally issued on July 5, 1994, to Pharmavene, Inc. ("Pharmavene") upon assignment from Edward M. Rudnic and George W. Belendiuk. Upon Pharmavene's merger with and into Shire Laboratories Inc. ("Shire Laboratories"), Shire Laboratories became the owner of the '570 patent. Upon the merger of Shire Laboratories into Shire, Shire became and remains the owner of the '570 patent. The '570 patent claims, *inter alia,* a drug delivery system for the oral administration of carbamazepine.

ANSWER: Teva USA admits that the '570 patent, entitled "Advanced Drug Delivery System And Method Of Treating Psychiatric, Neurological And Other Disorders With Carbamazepine," issued on July 5, 1994. Teva USA also admits that the '570 patent identifies the inventors as Edward M. Rudnic and George W. Belendiuk, and the assignee as Pharmavene, Inc. ("Pharmavene"). Teva USA does not have sufficient knowledge to form a belief as to the chain of ownership of the '570 patent. Teva USA also denies that paragraph 20 accurately describes what the

'570 patent claims. Teva USA denies the remaining allegations in paragraph 20 of the Complaint.

21. Pursuant to 21 U.S.C. § 355(b)(1), the '570 patent is listed in "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as covering Shire's Carbatrol® drug products.

ANSWER: Admitted.

22. Upon information and belief, Teva USA filed a paragraph IV certification for the '570 patent in its ANDA to obtain approval to engage in the commercial manufacture, use or sale of carbamazepine extended-release capsules before the expiration of the '570 patent.

ANSWER: Admitted.

23. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *Id.*

ANSWER: Teva USA denies that paragraph 23 is a full and accurate description of 21 USC § 355(j)(2)(B) and 21 C.F.R. § 314.95. Teva USA admits 21 U.S.C. § 355(j)(2)(B)(iv)(II) states that a notice is to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Teva USA admits that 21 C.F.R. § 314.95(c)(6) states that the contents of the notice are to include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." Teva USA also admits the detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

24. On information and belief, as of the date of Teva's Notice Letter (March 20, 2007), Teva was aware of the statutory provisions and regulations referred to in paragraph 23, above.

ANSWER: Admitted.

25. Teva's Notice Letter stated that Teva's ANDA does not infringe the '570 patent. Nevertheless, Teva's Notice Letter provided Shire with insufficient information regarding Teva's ANDA Products that are the subject of ANDA No. 78-592. Until Shire receives sufficient information from Teva, Shire cannot evaluate, confirm or test the correctness of Teva USA's certification that the '570 patent has not and would not be infringed. On information and belief, therefore, Shire alleges that Teva USA's submission to the FDA of ANDA No. 78-592 with a paragraph IV certification for the

'570 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '570 patent is an act of infringement of one or more claims of the '570 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva USA admits that Teva USA's Notice Letter stated that Teva USA's ANDA does not infringe the '570 patent. Teva USA also admits that Shire "alleges" that Teva USA's submission to the FDA of ANDA No. 78-592 with a paragraph IV certification for the '570 patent is an act of infringement of one or more claims of the '570 patent under 35 U.S.C. § 271(e)(2)(A). However, Teva USA specifically denies that the submission of ANDA No. 78-592 with a paragraph IV certification for the '570 patent is an act of infringement of one or more claims of the '570 patent under 35 U.S.C. § 271(e)(2)(A). Teva USA also denies the remaining allegations in paragraph 25 of the Complaint.

26. On information and belief, Shire alleges that Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of ANDA No. 78-592, carbamazepine extended-release capsules at the 100 mg, 200 mg, and 300 mg dosage strengths, will infringe one or more claims of the '570 patent.

ANSWER: Teva USA admits that Shire "alleges" that Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of ANDA No. 78-592, carbamazepine extended-release capsules at the 100 mg, 200 mg, and 300 mg dosage strengths, will infringe one or more claims of the '570 patent. However, Teva USA specifically

denies that any commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of ANDA No. 78-592 will infringe one or more claims of the '570 patent.

27. Upon information and belief, Teva has been aware of the existence of the '570 patent, making the acts of infringement set forth above deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Teva USA admits that Teva USA and Teva Ltd. were aware of the existence of the '570 patent prior to the submission of ANDA No. 78-592. Teva USA denies the remaining allegations of paragraph 28 of the Complaint.

28. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Teva is preliminarily and permanently enjoined by this Court.

ANSWER: Teva USA denies the allegations in paragraph 28 of the Complaint.

RESPONSE TO PRAYER FOR RELIEF

Teva Ltd. denies that Plaintiff is entitled to any relief whatsoever, let alone the relief requested in their Prayer for Relief.

AFFIRMATIVE DEFENSES

First Affirmative Defense

Teva USA's making, using, selling, importation of, or offering to sell the Teva ANDA products in the United States will not infringe any valid and enforceable claim of the '570 patent.

Second Affirmative Defense

In the event that Teva USA is found to infringe any of the claims of the '570 patent, such infringement is not and has not been willful.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Counterclaimant Teva Pharmaceuticals USA, Inc. ("Teva"), through its counsel, as and for its Counterclaims against Counterdefendant Shire, LLC. ("Shire"), states as follows:

The Parties

1. On information and belief, Shire is a corporation organized and existing under the laws of the State of Kentucky, having its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042.

2. Teva USA is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

Jurisdiction and Venue

3. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 2201 and 2202.

4. Personal jurisdiction of Plaintiff is proper by virtue of, *inter alia*, Plaintiff submitting to the jurisdiction of this Court through the filing of the present Complaint.

5. Subject matter jurisdiction over these controversies is proper under 28 U.S.C. §§ 1331 and 1338(a), 2201 and 2202.

6. Venue is proper under 28 U.S.C. §§ 1391 and 1400, and 21 U.S.C. §355(j)(5)(B)(iii)(III).

Background

7. Teva USA submitted Abbreviated New Drug Application ("ANDA") No. 78-592 ("Teva's ANDA") with the United States Food and Drug Administration ("FDA") for carbamazepine extended-release capsules at the 100 mg, 200 mg, and 300 mg dosage strengths ("Teva USA's carbamazepine products").

8. Shire has caused U.S. Patent Nos. 5,326,570 ("the '570 patent") and 5,192,013 ("the '013 patent") to be listed in the FDA "Approved Drug Products with Therapeutic Equivalence Evaluation" (commonly known as the "Orange Book") in connection with its NDA No. 20-712 relating to carbamazepine capsules.

9. By submitting the '570 patent and the '013 patent for inclusion in the FDA Orange Book, Shire has indicated that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21. U.S.C. § 355(b)(1).

10. Teva USA seeks FDA approval to market its generic carbamazepine products before expiration of the patents Shire listed in the Orange Book" Pursuant to 21 U.S.C § 355(j)(2)(A)(vii)(IV), Teva USA's ANDA includes a paragraph IV certification to the '570 patent and the '013 patent.

11. Under 21 U.S.C. §355(j)(2)(B)(i) and (ii), Teva USA provided Shire with notice that it made a paragraph IV certification with the FDA ("ANDA notice"). The ANDA notice included a detailed statement in which Teva USA set forth the bases for its

position that the manufacture, use, or sale of Teva USA's carbamazepine products will not infringe any claims of the '570 and '013 patents.

12. On information and belief, Shire received Teva USA's ANDA notice. With this notice, Teva USA offered Shire confidential access to its ANDA so that Shire could determine for itself that Teva USA's carbamazepine products would not infringe the '570 and '013 patents.

13. Under 21 U.S.C. § 355(j)(2)(B)(iii) and 35 U.S.C. § 271(e)(5), Teva USA was precluded from bringing a declaratory judgment action for 45 days after Shire received Teva USA's ANDA notice.

14. More than 45 days have now passed since Shire received Teva USA's ANDA notice.

15. On May 2, 2007, within that 45 day period, Shire sued Teva USA alleging infringement of the '570 and the '013 patents.

16. On August 24, 2007, Shire amended its complaint. The amended complaint alleges infringement of the '570 patent but not the '013 patent.

Counterclaim I
Declaration of Non-Infringement of the '570 patent

17. Teva USA realleges and incorporates by reference the allegations of paragraphs 1-16.

18. This claim arises under the Patent laws of the United States, 35 U.S.C § 1 et seq., and the Declaratory judgment Act, 28 U.S.C §§ 2201 and 2202, and 21. USC. § 355(j)(5)(C) ("Civil Action to Obtain Patent Certainty").

19. There is an actual controversy between Teva USA and Plaintiff concerning the issue of whether Teva USA's prospective manufacture, use, offer for sale, or sale of Teva USA's carbamazepine products will infringe claims of the '570 patent.

20. Based on Shire's listing of the '570 patent in the Orange Book, Teva USA's paragraph IV certification to the '570 patent, and the circumstances between Teva USA and Plaintiff with respect to the '570 patent, the parties' respective interests are adverse and sufficiently definite and concrete so as to warrant a declaratory judgment.

21. Teva USA is entitled to a declaration that the manufacture, use, offer for sale, or sale of Teva USA's carbamazepine products will not infringe any claim of the '570 patent.

Counterclaim II
Declaration of Non-Infringement of the '013 patent

22. Teva USA realleges and incorporates by reference the allegations of paragraphs 1-21.

23. This claim arises under the Patent laws of the United States, 35 U.S.C § 1 et seq., and the Declaratory judgment Act, 28 U.S.C §§ 2201 and 2202, and 21. USC. § 355(j)(5)(C) ("Civil Action to Obtain Patent Certainty").

24. Under 21 U.S.C § 355(j)(5)(C) ("Civil Action to Obtain Patent Certainty"), Teva USA is entitled to a determination that the '013 patent is not infringed by Teva's ANDA application.

25. In addition, based upon Shire's listing of the '013 patent in the Orange Book and Teva USA's submission of an ANDA with a paragraph IV certification directed to the '013 patent, the parties' respective interests are adverse and sufficiently definite and concrete so as to warrant a declaratory judgment.

26. Teva USA is entitled to a declaration that the manufacture, use, offer for sale, or sale of Teva USA's carbamazepine products will not infringe any claim of the '013 patent.

PRAYER FOR RELIEF

WHEREFORE, Teva USA prays that the Court enter:

1. An Order dismissing Plaintiffs complaint in its entirety;

2. A judgment that Teva USA's ANDA does not and will not infringe any valid and enforceable claim of the '570 patent.

3. A judgment that Teva USA's ANDA does not and will not infringe any valid and enforceable claim of the '013 patent.

4. An Order declaring this case "exceptional" pursuant to 28 U.S.C. § 285 and awarding Teva USA its costs and reasonable attorneys' fees; and

5. A judgment awarding Teva USA such other and further relief in its favor and against Plaintiff as the Court deems just and proper.

Dated: New York, New York
September 13, 2007

Respectfully submitted,

By: _____

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